This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

DEC 0 1 2008

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 51-R-0079
CUSTOMER NUMBER: 21555

FORM APPROVED
OMB NO. 0579-0036

Bridge Global Pharmaceutical Services Inc
610 Professional Drive
Gaithersburg, MD 20879

Telephone: (301) -987-1700

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (**Attach additional sheets if necessary or use APHIS Form 7023A**)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	551	50	3	604
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	102	0	0	102
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1096	38	10	1106
9. Non-human Primates	0	392	33	2	427
10. Sheep	0	0	0	0	0
11. Pigs	0	4	0	0	4
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

[redacted] b6,b7c

DATE SIGNED 12-24-08

(AUG 91)

b6,b7c

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3. Reporting Facility

Bridge Laboratories

[redacted] b2, b7f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

Column E Explanation

I. DOGS

Species: Beagle Dog
Study: [redacted] b4
Animal Number: 14158
Test Group/Sex: 4F
Justification:
Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug applications. The dog is [redacted] b4 studies. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.
Summary:
The purpose of this study was to [redacted] b4 a test article when [redacted] b4 Beagle dogs. Additionally, this study is designed [redacted] (b)(4) [redacted] (b)(4)

The animal completed two and a half weeks of dosing, and death occurred on Study Day 19. [redacted] b4 [redacted] (b)(4) [redacted] b4 also noted. At the AM mortality check, the animal was found dead.

Species: Beagle Dog
Study: [redacted] b4
Animal Number: 15877
Test Group/Sex: 1M
Justification:
Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug applications. The beagle dog is [redacted] b4
Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.

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Summary:
The purpose of this study was b4 b4 b4 beagle dogs. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

The animal completed seven weeks of dosing. The clinical observations b4 b4 s. On SD 50, approximately 1 hour and 20 minutes post-dose, the animal was found dead in his cage.

Species: Beagle Dog
b4
Animal Number: 15879
Test Group/Sex: 1M
Justification:
Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug applications. The beagle dog is b4
Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.
Summary:
The purpose of this study was b4 b4 beagle dogs. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

The animal completed two weeks of dosing. The clinical observations b4 b4 On (b)(4) the telemetry data for animal 15879 b4 . The animal was found dead approximately 2 hours and 20 minutes after dosing.

II. MONKEYS

Species: Monkey
Study: b4
Animal Number: 16437
Test Group/Sex: 3M
Justification:
This study was conducted in compliance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations for Non-clinical Laboratory Studies (21CFR Part 58. b4 b4 (b)(4) : most appropriate species for evaluating the safety of the test article. (b)(4) showed that the

test article [b4] Because this study was conducted in accordance with the regulatory guidelines, alternatives could not be considered.

Summary:
The purpose of this study was [b4] test article. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

[b4] The animal was found dead during PM mortality check on the same day.

Species: Monkey
Study:
Animal Number: 16451
Test Group/Sex: 4M
Justification:
This study was conducted in compliance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations for Non-clinical Laboratory Studies (21CFR Part 58. [b4] [b4] species for evaluating the safety of the test article. Previous [(b)(4)] studies undertaken showed that the [b4]s. Because this study was conducted in accordance with the regulatory guidelines, alternatives could not be considered.

Summary:
The purpose of this study was to evaluate [b4] test article. The following statement was included in this protocol: "In the event of severe toxicity in which decisions are to be made regarding treatment or euthanasia of a study animal, the [Bridge] Veterinarian and Study Director will preserve the right for subsequent action." The inclusion of this statement allows intervention aimed to alleviate pain or distress.

[b4]. The animal was found dead on [(b)(4)] observations.

III. RABBITS

Species: Rabbit
[b4]
Animal Number: Phase I: 16923-16928; Phase II: 16950, 16952-16954
Test Group/Sex: Phase I: 2F & 3F; Phase II: 4F & 4M
Justification:
The rabbit was selected because [b4]; [b4] Rabbits [(b)(4)]. Because this study in conducted in accordance with these regulatory guidelines, alternatives could not be considered.

Summary:
These animals were part of a two phase toxicity study. [b4] [b4]

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b4 All female animals dosed were found dead at 1.5 hours post-dose. b4

b4 During the PM mortality check three females and one male rabbit were found dead.